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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,874	05/15/1998	PATRICIA A. BILLING-MEDEL	6106.US.P1	8815

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.
09/079,874

Applicant(s)

Billing-Medall

Examiner

Karen Canella

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 23, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Dec 31, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

4. ☒ Applicant's reply has overcome the following rejection(s):
see attached
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: 31-54
Claim(s) objected to: none
Claim(s) rejected: 22-30
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other:

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Response to Arguments

1. The rejection of claims 22-54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to detect or diagnose urinary tract cancer, is withdrawn.
2. The rejection of claims 43-54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.
3. The rejection of claims 22-30 under 35 U.S.C. 112, first paragraph, for not provide enablement for polynucleotides having 95% identity over the full length of SEQ ID NO:1-12, is maintained for the reasons of record as set forth against variant having 70% identity to SEQ ID NO:1-12, on pages 3 to 4 Office action of Paper No. 13. Applicant has argues that one of skill in the art can readily make variants having 95% sequence identity to SEQ ID NO:1-12 by providing exhibit C regarding excerpts from the Wisconsin Sequence Analysis Package. This has been considered but not found persuasive. As stated in the Office action of Paper No. 13, a modification to a protein sequence can result in a completely different protein having different properties and functions as taught by Burgess et al and Lazar et al. Therefore, as a result of this unpredictability of protein function, one of skill in the art cannot anticipate the result of alterations in nucleic acid sequence and the specification has not provided objective evidence to support the allegation that polynucleotide variants having 95% sequence identity to SEQ ID NO:1-12 can be used in the diagnosis of urinary tract cancer, nor has the specification taught any specific alternative uses for the claimed polynucleotide variants.


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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 19, 2002


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SUPERVISORY PATENT EXAMINER
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